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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/770,403	02/04/2004	Timothy P. Murphy	010-001	2737

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EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3774

NOTIFICATION DATE	DELIVERY MODE
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04/30/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/770,403	Applicant(s) MURPHY, TIMOTHY P.	
	Examiner Paul B. Prebilic	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-14 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-14 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on April 7, 2008 has been entered.

Claim Rejections Based Upon Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-6, 8-10, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler et al (US 2002/0161414) in view of Ruiz (US 6,120,534). Flesler discloses a method of constricting the arteries leading to the small intestine with electrical stimulation but does not disclose placing a blood flow reducing device or an endograft inside the artery as claimed. However, Ruiz teaches that it was known to use

physical restriction devices in arteries in order to restrict blood flow where needed; see the figures (particularly Figures 8A to 8C), the abstract, column 2, lines 5-58, and column 7, line 21 to column 8, line 16. Therefore, it is the Examiner's position that it would have been obvious to utilize the endograft device of Ruiz in conjunction with or partly in place of the electrical stimulation device of Flesler to provide a set degree of minimal constriction that can be varied with the electrical stimulation means of Flesler or for the same reasons that Ruiz utilizes the same.

With regard to claims 3 and 8, the electrodes (200) of Flesler are devices placed around (i.e. in the area of) arteries of the small intestine including the superior mesenteric (110); see Figure 4. For this reason, the Examiner asserts that the claim language is clearly obvious over Flesler as modified by Ruiz.

With regard to claims 5 and 6, Flesler teaches putting electrodes in arteries leading to the small intestine. Since the gastroduodenal artery leads to the small intestine, the use of a constriction device therein is clearly suggested.

With regard to claim 12, Ruiz clearly teaches expanding the constrictor to adjust the amount of blood flow; see *supra*. For this reason, such would have been obvious when utilized in Flesler's method.

With regard to claim 13, a "swellable material" is interpreted broadly to mean a material that is able to increase in size or expand in size or shape; see <http://encarta.msn.com/encnet/features/dictionary/DictionaryResults.aspx?refid=1861717507>. Clearly, the middle portion of the Ruiz device is a material that can be increased in size and shape; see *supra*.

With regard to claim 14, the Examiner asserts that it would have been obvious to manage pain or discomfort by adjusting the constriction in order to maximize the benefit of the device where utilized.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Flesler and Ruiz as applied to claims 1, 3-6, 8-10, and 12-14 above, and further in view of Yurek et al (US 5,690,644). Flesler fails to disclose moving a sleeve over the endograft and removing the sleeve within the artery. However, Yurek teaches that it was known to utilize sleeves over stents with inner catheters; see Figure 1 and column 3, lines 46-58. Therefore, it is the Examiner's position that it would have been obvious to utilize a sleeve with the stent and catheter of Flesler for the same reasons that Yurek utilizes the same, in order reduce artery tissue damage during delivery or to better control expansion of the constrictor.

Claims 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Flesler et al (US 2002/0161414) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Flesler et al (US 2002/0161414) in view of Ruiz (US 6,120,534). Flesler anticipates the claim language where electrical stimulation is used to constrict the arteries leading to the small intestine; see paragraphs [0020], [0011], and [0113]-[0114]. The reduction is considered to be permanent, fixed, invariable, and continuous to the extent required because these terms are terms of relative degree. Therefore, the Flesler device can and is used for permanent, fixed, invariable, and continuous way at least for a period of time.

Alternatively, one may not consider these terms of degree met by Flesler because Flesler teaches that the amount of reduction can be varied and transient. However, Ruiz teaches that it was known to the artery treatment art to make blood flow reduction more permanent, fixed, invariable, and continuous; see the previously cited portions thereof. Therefore, it is the Examiner's position that it would have been obvious to utilize the Ruiz device in addition to the Flesler device to provide a set degree of minimal constriction that can be varied with the electrical stimulation means or for the same reasons that Ruiz utilizes the same.

Response to Arguments

Applicant's arguments filed April 7, 2008 have been fully considered but they are not persuasive.

In response to the traversal that the NIH panelists' skill levels are "higher than that of a routineer in these arts" (see page 2 of the response filed April 7, 2008), the Examiner notes that they are not be qualified to determine obviousness under Section 103 because it requires one of ordinary skill. Furthermore, the panelists did not evaluate obviousness of the claimed methods, but rather, only looked at Mr. Murphy's methods for safety and efficacy.

Additionally, statements made in the Summary Statements pertaining to the state of the art were not correct. In particular, the Summary Statement of John Haller made of record on July 12, 2007 (see page 2, lines 6-9 of the text) suggests that reducing "mesenteric arterial blood flow" was "novel." However, Flesler (US 2002/0161414) discloses that a method of doing this was known in the patent literature well before the

publication of Summary Statement; see paragraph [0020] of Flesler. As a result, it is fairly clear that the panel and/or the author of this Summary Statement was not aware that this method was known. Moreover, it demonstrates that the panel members and/or the statement author were not evaluating the obviousness of the claimed invention in view of all the prior art.

Similarly, the Summary Statement by Christine Densmore made of record on July 12, 2007 (see page 2, third paragraph thereof), suggests that stents that restricted blood flow were not known on the date this Statement was published March 23, 2006. However Ruiz (US 6,120,534) demonstrates that the same was known to the patent literature at least 5 years before; see Figures 8A to 8C, the abstract, column 2, lines 5-58, and column 7, line 21 et seq. Therefore, the Examiner asserts that the author of the Statement and/or the NIH panel was not knowledgeable of the state of the patent art.

In response to the evidence that the NIH panel evaluating Dr. Murphy's proposed method were of a high skill level, it is noted that only 1 of the 14 investigators (panel members) were on the scientific panel that evaluated Dr. Murphy's proposal (see the 14 biographies, curricula vitae, or the like made of record on April 7, 2008). For this reason, the backgrounds of 13 of the panel members are not clearly related to the present patentability determination. Furthermore, even though Dr. Burgess-Beusse was listed as a panel member on one of Summary Statements, the actual substance of the Summary Statement suggests that she was not aware of the state of the patent art at the time the statement was made.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). The Examiner maintains that the motivation to combine Flesler and Ruiz is clearly demonstrated in the applied prior art and articulated in the rejection statement. The Examiner asserts that Flesler and Ruiz are clearly in the same art or in at least analogous arts of blood flow control. For this reason, the Examiner maintains that there is a clear nexus between them.

For these reasons, the Applicant's arguments were not considered persuasive and the rejections have been maintained.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774